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Telemedicine: The Concept and Legal Regulation in Russia, Europe, and USA

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Abstract

This article is devoted to a comparative legal analysis of the concept and legal regulation of telemedicine in Russia, Europe (on the example of the EU), and the USA.

Telemedicine, the problems of using telemedicine technologies in the provision of medical care are relevant objects of scientific research and discussion both for medicine and law (medical law, civil law). Telemedicine issues have become especially significant in connection with the introduction of Federal Law No. 242-FZ of July 29, 2017 "On Amending Certain Legislative Acts of the Russian Federation on the Use of Information Technologies in the Field of Health Protection", which legalized the use of telemedicine in Russia.

In the framework of this comparative study of the concept of "telemedicine", the article analyzes the definitions of this term, enshrined in the laws of these countries, as well as the definitions available in science and practice. Attention is also being paid to the definition of "telemedicine" given by the World Health Organization.

The analysis of the legal regulation of telemedicine considers the relevant sources of legal regulation in Russia, the EU, and the USA, and allows drawing conclusions about the existing problems of legal regulation and gaps in the legislation.

Keywords: Telemedicine, Telemedicine technologies, Legal regulation, Telehealth, Medical care.

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Introduction

Telemedicine, the use of telemedicine technologies in the provision of medical care is one of the current trends in the development of the modern healthcare system. The special importance of telemedicine technologies is manifested in the fact that its use can prove access to more qualified medical care for certain social groups that have difficulties in obtaining medical care directly in medical institutions. Such social groups may include the elderly, people living in hard-to-reach areas, prisoners, “whose movement is difficult due to the security system” [1, p.32], and disabled people.

However, despite the importance of telemedicine for providing medical care to people and the relative prescription of the appearance of this institution in theoretical medicine and science, as noted by M. S. Variushin, the phenomenon itself has been known to theoretical medicine since the mid-19th century (2, p.165). However, some countries of the world still don't have full-fledged legal regulation of this institution, or legal regulation has been introduced relatively recently, or telemedicine, in principle, has not yet been used.

For example, the legal regulation of telemedicine in Russia was introduced only in 2018. Namely, from January 1, 2018, the Federal Law of July 29, 2017 No. 242-FZ "On Amending Certain Legislative Acts of the Russian Federation on the Use of Information Technologies in the Field of Health Protection" [3] (hereinafter - Federal Law No. 242-FZ), which amended the Federal Law of November 21, 2011 No. 323-FZ "On the Basics of Protecting the Health of Citizens in the Russian Federation" [4] (hereinafter - Federal Law No. 323-FZ).

Over the past period, there has not yet been formed any sustainable practice of applying the changes introduced in Federal Law No. 323-FZ. Although scientists and practitioners have already criticized the nature and quality of the introduced provisions on telemedicine.

In connection with the foregoing, a comprehensive study of the concept and legal regulation of telemedicine according to Russian legislation seems relevant. To this end, the authors of this article find it promising to turn to a comparative legal analysis of the concept and legal regulation of telemedicine in Russia, Europe (on the example of the European Union, hereinafter referred to as the EU), and the USA.

Methods

The methods of this article are general scientific and special methods. The applied general scientific methods are as follows: universal dialectic, historical, method of system analysis, synthesis, induction, deduction. Among the special ones, we can single out the formal legal method of comparative law, and the system-structural method.

Results And Discussion

The comparative legal analysis in this article will address two main issues: the concepts of telemedicine (based on interpretations of the term in legislation, science, and practice) and the legal regulation of telemedicine (a brief but comprehensive analysis of the sources will be provided).

Before turning to a direct comparison of this concept in Russia, Europe (EU), and the USA, we turn to the definition of "telemedicine" given by the World Health Organization:

telemedicine is "the provision of health services in the distance-critical conditions by health workers using information and communication technologies to exchange the necessary information for the diagnosis, treatment and prevention of diseases and injuries, conducting research and evaluations, as well as for continuing education of medical workers in the interest of improving public health and developing local communities" [5].

In our opinion, this definition is quite capacious, and qualitatively reflects the essence of this institution, and may or could be taken as a basis by states in the development of legislative provisions.

Turning to the Russian legislation, we note that the concept of "telemedicine" has not been directly embodied in Russian legislation. Instead of the term "telemedicine", paragraph 22 of part 1 of article 2 of Federal Law No. 323-FZ contains the definition of "telemedicine technology":

these are the "information technologies that provide for remote interaction of medical workers among themselves, with patients and (or) their legal representatives, identify and authenticate specified persons, document their actions during consultations, consultations, and remote medical monitoring of their condition" [4].

The definition of "telemedicine technology" is quite substantial, and, at first glance, it might seem that "telemedicine technology" is almost the same as "telemedicine". However, one should disagree with this. The term "telemedicine" is broader than "telemedicine technology" and can have several meanings with different semantic meaning: telemedicine is not only the provision of health services using appropriate technologies but also a separate phenomenon [2, p. 165] in medicine and science [5], etc. Telemedicine technologies are precisely the technologies that provide for remote interaction. Consequently, telemedicine includes telemedicine technology.

The legal regulation of telemedicine can be divided into two large blocks: the first is devoted directly to the provision of medical care; the second is devoted to the protection of personal data [2, p. 169]. The first block includes the aforementioned Federal Law No. 323-FZ (clause 2 of Part 1 of Article 2, Article 36.2), and its accompanying by-laws (resolutions of the Government of the Russian Federation, orders of the Ministry of Health of the Russian Federation (for example, Order of the Ministry of Health of Russia dated November 30, 2017 No. 965n "On Approval of the Organization and Provision of Medical Care Using Telemedicine Technologies" [6]).

Although the legal regulation of telemedicine in Russia was introduced relatively recently (Federal Law No. 242-FZ entered into force on January 1, 2018), it is already clear that the established legal norms contain some gaps and shortcomings. For example, there are problems associated with the availability of medical care using telemedicine technologies for the entire population (the problem of using an enhanced qualified electronic signature).

Next, we shall consider the European experience.

According to the European Commission, telemedicine can be defined as “the provision of medical services through the use of ICTs in situations where the health care provider and patient (or two medical specialists) are not in the same place. It includes the safe transfer of medical data and information through text, sound, images or other forms necessary for the prevention, diagnosis, treatment, and monitoring of patients” [7].

In our opinion, this definition of the European Commission, although it contains the main features that reflect the essence of the institution in question, has its drawbacks. Firstly, it is not specified how exactly the ICT-based medical services can be provided - in the form of consultations, consultations, etc. Secondly, the definition provided by the European Commission, by the way, as well as in the definition of "telemedicine technologies" under Russian law, contains no indication of the education of medical workers through remote interaction.

However, the mentioned omissions in the definition of "telemedicine" given by the European Commission do not mean that telemedicine has not found a diverse and multitasking application in practice in Europe. On the contrary, as noted in scientific studies devoted to the analysis of this topic, telemedicine can cover very different realities [8]. Remote interaction can occur both in real time and at intervals; various devices can be used for communication between participants [9, p.1].

The legal regulation of telemedicine in Europe within the European Union is characterized by the following main features.

Firstly, there are two levels of legal regulation of telemedicine: the first represents supranational legislation - it refers to various EU directives and other regulatory documents, the second is composed of national legislation of the EU member states. This double regulation leads to certain problems. Supranational legislation has its own approach to the legal regulation of telemedicine, while EU member states have a different approach. In addition, some EU countries also have no single view on the legal regulation of telemedicine [9, p.4].

Secondly, the dualism of supranational legal regulation of telemedicine. Telemedicine in the framework of European law is actually both a health service and information service [9, p.3]. Accordingly, supranational legal regulation falls into two groups [2, p.166]: the first group consists of standards in the provision of medical services (Directive of the European Parliament and of the Council of the European Union of 09.03.2011 No. 2011/24/EU “On the rights of patients in cross-border medical care” [10]), the second - in the field of information services and the protection of

personal data (for example, EU Directive of 08.06.2000 No. 2000/31/EU “On some legal aspects of the provision of information services to the public, in particular electronic commerce, in the domestic market” [11]). There are also various program documents, telemedicine projects. However, many issues remain unresolved by supranational legislation, therefore, these issues are the responsibility of the EU Member States, which creates a problem due to the lack of a unified approach to telemedicine among EU members.

Thirdly, the third feature follows from the first two, which is also one of the problems in the legal regulation of telemedicine within the EU - the lack of a single code/set of standards in the field of telemedicine. The existing problems in legal regulation pose a threat to the development of telemedicine in general.

Having analyzed the experience of the United States on the topic, we can confidently say that the United States has no single definition of "telemedicine." There are several reasons for this.

Firstly, the legal regulation of telemedicine in the USA is carried out at two levels: the federal and the state level. It follows that there are many different definitions of telemedicine. For example, “the law of the State of Mississippi (Miss. Code Ann. § 73-25-34) defines telemedicine as the transmission by electronic or other means of information containing medical opinion...” [1, p. 33], while “the law of California (Cal. Health and Safety Code § 1374.13) recognizes telemedicine as a way to receive medical services” [1, p. 33].

Secondly, some organizations in the USA use the term “telemedicine” interchangeably with the term “telehealth”, although “telehealth” is essentially interpreted broader than “telemedicine” [12, p. 567].

Thirdly, in addition to the legal regulation of “telemedicine” at the federal and state levels, the definition of “telemedicine” or “telehealth” is given by various government organizations in the field of health (for example, Health Resources and Services Administration (HRSA)).

Fourth, despite the long-standing emergence of the institute of telemedicine in the United States (originated from the late 1960s [13, p. 6473]) and its existence for a longer time compared to many other countries, there is no standard nomenclature in the provision of medical care through telemedicine [14-16].

Speaking about the legal regulation of US telemedicine, in addition to two-level regulation, the following should be noted. At the federal level, the legal regulation of telemedicine in the USA is carried out by the Health Insurance Portability and Accountability Act (HIPAA) of 1996; rules on security, privacy, etc., adopted in its development; by-laws and regulations of various organizations [1, p.32]. At the state level, their adopted laws or codes apply. In addition, telemedicine/telehealth legislation is periodically revised in the United States.

Summary

The authors of this article have arrived at the following conclusions:

1. The Russian legislator introduced in Federal Law No. 323-FZ a narrower concept of "telemedicine technologies" than the concept of "telemedicine" used in world science and practice. It is difficult to answer yet how critical it is. In our opinion, this is more an omission rather than an advantage.
2. There are gaps in the introduced Russian telemedicine standards that need to be addressed.
3. The definition of "telemedicine" given by the European Commission contains some disadvantages.
4. The EU legislation has no single code of practice on telemedicine, which impedes the development of telemedicine.
5. There is no single definition of telemedicine in the United States. Some organizations interpret telemedicine and telehealth interchangeably.
6. The two-level legal regulation of telemedicine (federal and state law) is distinguished by a systemic and sustainable nature. At the same time, legislation is periodically subject to revision.

Conclusions

Based on the study, the authors propose the following:

1. Along with the term "telemedicine technologies", paragraph 1 of Article 2 of the Federal Law No. 323-FZ can be supplemented with the concept of "telemedicine".
2. Russian telemedicine legislation requires its further reform.
3. It is possible to make additions to the definition of the European Commission on telemedicine: it is possible to add ways to provide medical care through telemedicine (consultations, etc.) and indicate another option for telemedicine - the education of medical workers.
4. In EU legislation, it seems promising to introduce a single code of practice to govern telemedicine.
5. It seems more reasonable to distinguish between the concepts of "telemedicine" and "telehealth" in the United States, and do not use them interchangeably in view of the existing difference in concepts.
6. The US experience in the legal regulation of telemedicine can be taken as a basis for further reform of Russian and EU legislation in the field of telemedicine.

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